AWARD NUMBER: W81XWH-15-1-0149

TITLE: Tactile Sensing Reflexes for Advanced Prosthetic Hands

PRINCIPAL INVESTIGATOR: Jeremy A. Fishel, PhD

CONTRACTING ORGANIZATION: SynTouch, LLC
Los Angeles, CA 90007

REPORT DATE: October 2016

TYPE OF REPORT: Annual

PREPARED FOR: U.S. Army Medical Research and Materiel Command
Fort Detrick, Maryland 21702-5012

REPORT DOCUMENTATION PAGE

Form Approved
OMB No. 0704-0188

1. REPORT DATE	2. REPORT TYPE	3. DATES COVERED
October 2016	Annual	30 Sep 2015 - 29 Sep 2016

4. TITLE AND SUBTITLE
Tactile Sensing Reflexes for Advanced Prosthetic Hands

5a. CONTRACT NUMBER

5b. GRANT NUMBER
W81XWH-15-1-0149

5c. PROGRAM ELEMENT NUMBER

6. AUTHOR(S)
Jeremy A. Fishel, Gary M. Berke, Blaine Matulevich, Kelsey A. Muller, Raymond Peck

E-Mail: jeremy.fishel@syntouchllc.com

5d. PROJECT NUMBER
0010678343

5e. TASK NUMBER

5f. WORK UNIT NUMBER

7. PERFORMING ORGANIZATION NAME(S) AND ADDRESS(ES)

SynTouch
2222 S FIGUEROA ST PH 2
LOS ANGELES CA 90007-6601

8. PERFORMING ORGANIZATION REPORT NUMBER

54VB3

9. SPONSORING / MONITORING AGENCY NAME(S) AND ADDRESS(ES)

U.S. Army Medical Research and Materiel Command
Fort Detrick, Maryland 21702-5012

10. SPONSOR/MONITOR'S ACRONYM(S)

11. SPONSOR/MONITOR'S REPORT NUMBER(S)
W91ZSQ

12. DISTRIBUTION / AVAILABILITY STATEMENT

Approved for Public Release; Distribution Unlimited

13. SUPPLEMENTARY NOTES

14. ABSTRACT

The purpose of this research is to develop and clinically validate a novel tactile sensing technology and control algorithm to improve grasping performance in amputee users of myoelectic prosthetic hands. The planned scope of research for this reporting period were to: 1) develop and evaluate improved tactile sensors to be used in future clinical studies, 2) make progress on the development of customized electronic controllers for these prosthetic hands, and to 3) design novel outcome measures and submit the plans for able-bodied human research to validate these novel measures for IRB/HRPO approval. Specific aim 3 is ahead of schedule and IRB/HRPO approval has been obtained and data collection is currently underway. Major findings during this reporting period include 1) the design and construction of novel robust sensor designs and testing of these designs, 2) development of a controller development board to test the programming and function necessary for clinical testing, and 3) the development of novel outcome measures to evaluate visual and cognitive distraction while grasping and the IRB/HRPO approval to validate these measures with able-bodied subjects.

15. SUBJECT TERMS
tactile sensing, prosthetic hands, grasping, reflexes, clinical studies, outcome measures, visual distraction, cognitive distraction

16. SECURITY CLASSIFICATION OF: Unclassified			17. LIMITATION OF ABSTRACT	18. NUMBER OF PAGES	19a. NAME OF RESPONSIBLE PERSON
a. REPORT	b. ABSTRACT	c. THIS PAGE			19b. TELEPHONE NUMBER *(include area code)*
Unclassified	Unclassified	Unclassified	Unclassified		USAMRMC

Table of Contents

1. INTRODUCTION:

The purpose of this research is to equip a myoelectric prosthetic hand with contact detecting sensors and a custom controller that enables a biomimetic reflex to improve the speed and ability to perform fragile grasping tasks for amputees. This hand would reduce the variability in grasping performance with delicate object thereby reducing the cognitive load associated with these difficult tasks. The battery life of the prosthesis would be conserved by applying appropriately low forces when needed without an effect on the maximum force and performance capabilities of the hand. In this research, the outlined technology will be developed and assembled including customized sensors, firmware, and a controller board. Clinical studies will be performed in order to first, develop baseline outcome measures of fragile grasping and second, to test the product in the field with myoelectric prosthesis users to ensure that user-benefit objectives have been met.

2. KEYWORDS:

Myoelectric Prosthesis, Outcome Measure, Volunteer Study, Fragile Grasp, Cognitive Load, Low Force, Sensors, Firmware, Controller, Amputee

3. ACCOMPLISHMENTS:

What were the major goals of the project?

1-1 Design and Fabrication of NumaTac Prototypes:

- Initial design review meetings (0-1 mos.) 100%
- Design sensor electronics and signal conditioning (1-2 mos.) 100%
- Design core and foam parts for all configurations of VariPlus Speed thumbs and fingers (1-2 mos.) 100%
- Order PCBs and components and assemble 25 electronics prototypes (2-4 mos.) 70%
- Manufacture 24 plastic cores for medium sized VariPlus Speed thumbs to be used for prototype development and verifications (2-3 mos.) 100% (plastic breaks, abandoned plastic prototyping)
- Identify candidate foam materials and processes to meet mechanical requirements and specifications (2-3 mos.) 100%
- Over-mold plastic cores for thumb using various candidate foam materials and processes (4-5 mos.) (Abandoned, plastic cores not durable enough)
- Assemble first batch of NumaTac prototypes (6 mos.) 80%

1-2. Verification of Requirements and Final Design Selection:

- Design and build cyclic loading evaluation equipment (4-6 mos.) 100%
- Verify requirements for electronics power consumption (7 mos.) 100%
- Verify requirements for static loading (7-8 mos.) 100%
- Verify requirements for durability under cyclic loading with cosmesis (7-8 mos.) 100%
- Perform cost analysis of NumaTac design and verify requirements for production costs (7-8 mos.) 100%

- Measure compliance and sensitivity of candidate foam materials and processes for NumaTac prototypes with cosmesis (7-8 mos.) 100%
- Design reviews and evaluations (as needed) (7-8 mos.) 80% (ongoing)
- Select the candidate foam material and process that meets commercial requirements and has best performance in sensitivity and compliance (9 mos.) 50%

2-1. Build, assemble, test prosthetic hand with sensors and controller

- Design/order/build electronics boards and electrical wiring (8-10 mos.) 70%
- Manufacture two NumaTac sensors for medium-sized VariPlus Speed fingertips (10-11 mos.) 60%
- Program controller to perform contact detection reflex (11-13 mos.) 80%
- Program controller to perform software functions for clinical studies (12-13 mos.) 60%
- Evaluate software functions for clinical studies in bench testing (13-15 mos.) 20%
- Evaluate performance in fragile grasping in bench testing (13-15 mos.) 10%
- Evaluate software functions for clinical studies in bench testing (13-14 mos.) 0%
- Evaluate performance in fragile grasping in bench testing (13-15 mos.) 0%
- Debug software (as needed) (11-16 mos.) 25%
- Manufacture prostheses for each subject in clinical studies (as needed) (24-36 mos.) 0%
- Design reviews and evaluations (as needed) (9-48 mos.) 20%
- Provide technical support (as needed) (16-48 mos.) 10%

3-1. Develop grasping evaluation protocol and perform outcome measure validation study

- Evaluate fragile grasping candidate objects based on strength and deformation (0-3 mos.) 100%
- Design and build “mechanical egg” test equipment (1-2 mos.) (Abandoned, alternate approach developed)
- Develop experimental protocol for timed trials in grasping fragile objects (3-4 mos.) 100%
- Evaluate methods of distraction when performing tasks (0-3 mos.) 100%
- Design and build necessary software and hardware for performing tests (3-4 mos.) 100%
- Develop experimental protocol for timed trials in grasping fragile objects (4-6 mos.) 100%
- Refine eligibility criteria, exclusion criteria, screening protocol for outcome measure validation and finalize consent forms (7 mos.) 100%
- Submit documentation for IRB exemption (7-8 mos.) 100%
- Submit Military 2nd level IRB review (HRPO) (12-15 mos.) 100%
- Recruit 30 normal volunteers and perform studies (16-17 mos.) 35%
- Analyze all outcome measure candidates to determine their reliability between tests and retests, and between raters (17 mos.) 25%
- Select outcome measures to be used in clinical studies (18 mos.) 50%

4-1. Conduct in-office and in-the-field clinical studies (not yet started)

4-2. Conduct clinical studies (not yet started)

4-3. Prepare academic submissions and documentation (not yet started)

What was accomplished under these goals?

Major Task 1-1: Design and fabricate NumaTac Prototypes

- Benchtop Testing and Design Identification: Initial and review meetings took place in order to identify designs, materials, and modifications that should be researched.
    - Meetings were held with *Foam Molders* (Cerritos, CA), to identify viable material and manufacturing options. In parallel, options for creating an air-tight seal around the sensor including ripstop fabrics, glues, coatings, and elastomers were identified, ordered, and tested in bench top tests. It was determined that a thin polyurethane film sleeve, heat sealable ripstop nylon, and a manufactured silicone skin were the three most viable, air tight and durable options. A manufacturer for the polyurethane sleeve was identified and a design was developed and manufactured for final sensor testing.
- Fabrication: An initial batch of finger sensor aluminum cores were designed and manufactured. It was determined after receiving testing information from Ottobock (Austria) that the finger core would need to have a more bulbous tip to prevent the thumb and finger from sliding past one another and damaging the sensors. After this, three new finger and thumb cores were designed to address this problem and interface with the hand, cosmetic glove, and current foam molding practices. These core designs include pressure sensor pockets within the foam and one with the sensor pocket outside of the foam. These core candidates have been ordered, and are having pressure relief holes laser drilled. A custom flexible component board that holds the pressure sensor has been made for an integrated design that should improve sensitivity for use during testing.
    - We are waiting to receive all aluminum cores overmolded with 4 candidate foam materials that vary in durability and deformability and have been identified as viable candidates according to specifications. For these foams, there are different treatments for creating airtight seals including spray sealing of different thicknesses and RF sealed polyurethane sleeves. The chosen sealing method depends on the core design, foam material, and density of foam.

Major Task 1-2: Verify commercial requirements and performance specifications and select final design

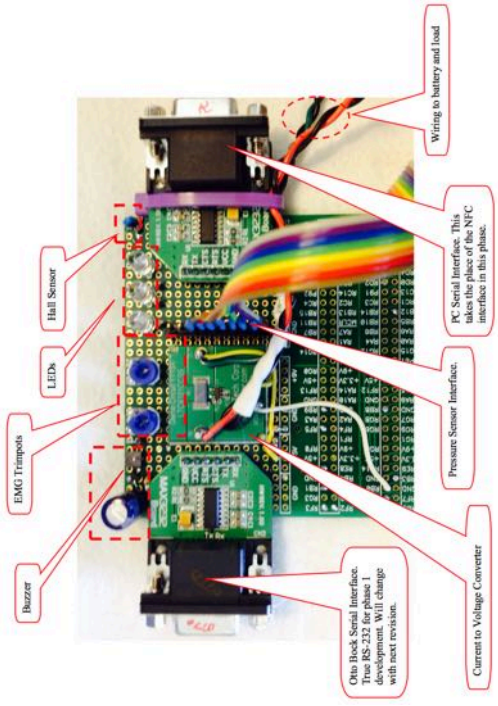
- Analysis of our computational model has allowed us to identify key parameters to optimize to improve the performance of our sensor and control its sensitivity threshold.

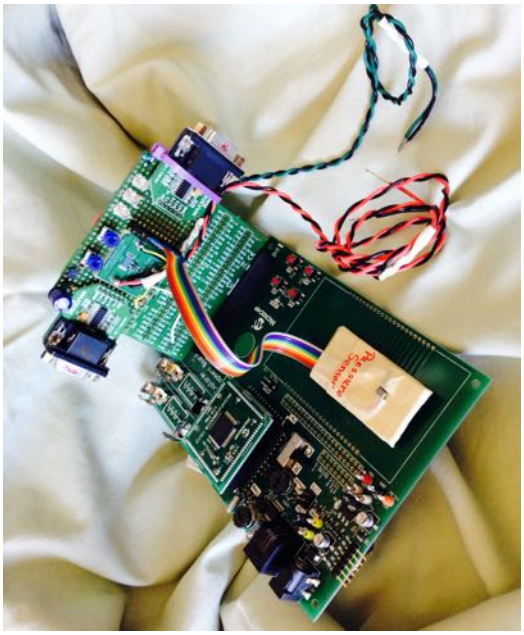
- Static and cyclic loading requirements of the hand and sensors were verified. Testing equipment for the evaluation of sensor durability under static and cyclic loads was designed, sourced, assembled, and tested. Cyclic loading will be applied using a pneumatic gripper producing 100N of force on the sensors for 500,000 grasps, which is consistent with the prosthetic hand warranty. Software has been developed to control the behavior of the gripper including force, rate, and number of grasps. The static loader is designed to apply 300N of force to the end of the finger sensor. New hands have been ordered for testing.
- Requirements for power consumption were identified and verified. It is required that each sensor draws <1mA. The evaluation of the sensor and associated electronics to be used verified that we should expect 0.02mA power consumption for each sensor. This is based on a safe estimate of 500 grasps/day and an average usage time of 8 hours/day.

Major Task 2-1: Build, assemble, and test prosthetic hand with NumaTac sensors and controller

Controller:

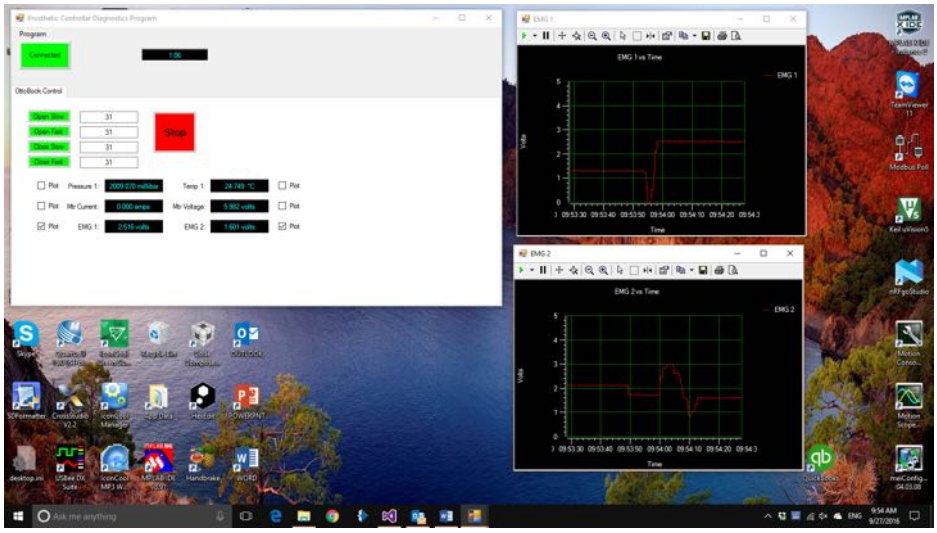
- An ideal pressure sensor was sourced and ordered to optimize sensitivity, size, and cost.
- Comprehensive documentation has been developed on the requirements for the prosthetic hand controller and associated electronic components. A layout and breadboard version of the controller has been designed and developed to verify that functional, power, and storage specifications are met. This breadboard electronic circuit validates the proposed electronics circuitry between the EMG electrodes (input), hand motor (output), and contact event information from the sensors. A schematic for the controller can be found in Appendix A.
- After the breadboard circuit development, revisions and improvements were made including a 5V interface and regulator and a change to the power supply. This final design has been tested and current consumption using all three sensors is consistent with our specifications. The components, circuitry, and geometry of this development board are now in the final format and in production. Documentation and a bill of materials have been created for this final format of the prosthetics hand controller. Photos of the completed breadboard are found here:





Firmware:

- A list of requirements for the firmware associated with the prosthetics controller has been developed. These requirements include directions for operating the hand, reading sensor data, implementing reflex behavior, recording diagnostic behavior, downloading data, and communicating via BTLE to change parameters. Two firmware experts were identified and Chris Kepner was chosen to produce firmware, which has been completed and tested with the prosthetics controller hardware. The development board is now successfully executing code, communicating with analog inputs and the DMA controller, and talking to the pressure sensor chip through the SPI bus. The pressure and temperature sensors are being read, the processor is communicating to the PC using the UART-USB bridge chip and a PC diagnostics program has been written for control of the prosthetic hand and viewing of the sensor analog inputs. Overall, the firmware is in final stages and successfully integrating with the electronics circuitry. A screenshot of the functioning firmware displaying EMG and a sensor pressure signal are found here:



Major Task 3-1: Develop protocol for evaluating grasping and perform studies to validate these outcome measures

- A performance study was conducted in order to evaluate fragile grasping candidate objects based on strength and deformation. The final object, saltines, stood out as the best choice because they are fragile and break in a distinct way, leaving little room for subjectivity on the part of those conducting studies. It was decided that an every-day object like this is the best for evaluating fragile grasping because the task is both realistic and grip forces are easy for the subjects to estimate; therefore, the idea of a "mechanical egg" or force measuring object was rejected in favor of this common cracker.

- A comprehensive bench top study was conducted in order to identify effective outcome measures for the evaluation of fragile grasping for myoelectric prosthesis users. Methods of visual and cognitive distractions that were evaluated for their effect on grasping performance of an amputee included but were not limited to visual occlusion (full, partial, augmented) mathematical calculations, question answering, spelling and word associations, decision making, etc. The best distraction methods were identified as visual occlusion and parallel story summarization. An amputee, Vikram Pandit, performed timed preliminary experiments both bimanually and unimanually. A summary of experiments performed can be found below and the downfalls of the experiment are shown with "X's", while promising results are shown with checks.

Outcome Measures Summary:

Visual Distractions

Visual Impairment Goggles

- Two different types of visual impairment goggles were used, one that blurs vision, and one that warps vision. A unimanual cracker passing task was conducted where the subject is presented with a cracker and transfers it to a cup. This was done without wearing goggles and while wearing a pair of goggles.

× *With goggles, the subject was significantly slower with their sound hand (52%) and VPS (32%) hand than with the NT hand (14%). The sound hand is the "easiest hand to use" however performance decreases more with the sound side than NT hand. This is a problem – we cannot correlate % speed decrease to how difficult it is to use a given prosthesis using this measure.*

× *The subject felt sick wearing the goggles for too long. It is evident that they distort vision so much that when the subject closed their eyes to avoid looking through the goggles, they actually performed better. The goggles are too difficult to use and may actually make subjects sick.*

Visual Barrier

- The subject is instructed to grasp a cracker with the sound hand, pass it to the prosthetic hand behind a large barrier that obstructs view, and transfer that cracker to a cup using the prosthetic hand.

× *With a relatively rapid task, the barrier tended to obstruct the movement of the subject often enough that task time was affected.*

✓ *Speed dropped more with VPS (21%) than the NT (13%)*

× *More dramatic numbers were measured when vision was occluded completely with a blindfold and therefore we decided that the barrier is too much of a hassle and the process can be simplified with better results by removing vision completely.*

Unimanual Blindfolded Passing

- The subject is instructed to grasp a cracker with the prosthetic hand and transfer that cracker to a cup. This was done with the subject wearing a blindfold.

× *It was difficult for the subject to grasp a cracker with the prosthesis if they are not holding it. They have no way to know where it is.*

✓ *It is possible to compare performance to the sound side.*

Bimanual Blindfolded Passing

- The subject is instructed to grasp a cracker with their sound hand, pass to their prosthetic hand, and transfer that cracker to a cup. This was done with the subject wearing a blindfold.

✓ *Performance speed decreased significantly more when using the VPS (80%) than the NT (16%) or sound side hands (21%).*

✓ *The task is very simple.*

× *It is a little difficult for the subject to find the initial cracker, therefore it needs to be placed in the same spot every time it is presented.*

× *We cannot compare to the subject's sound side, therefore we will need to compare to able-bodied individual's performance.*

Cognitive Distractions

A one-to-one task is a series of tasks with one occurring with each cracker pass. A parallel task is a single task that spans for the duration of the experiment.

Math Problems & Odd/Even Sum (one-to-one)

- The subject is presented with two random single digit numbers at the same time that they are presented with a cracker. They are instructed to add the two numbers and dictate whether the sum is odd or even before dropping the cracker into the cup, upon which they will be presented with two new numbers. This is a unimanual passing task. This is repeated 10 times, once for each cracker that is grasped. Time, cracker breaks, and addition failures are recorded.

× *The cognitive portion of this task slowed the subject's passing speed when using the sound hand, Vari-Plus Speed (VPS) hand, or the NumaTac hand (NT). There was no significant difference in worsening percentage (WP) between the VPS or NT hands and therefore is not a good method to compare difficulty of use between the two hands.*

× *Addition introduces performance anxiety, which may affect a person's performance and comfort level with the task.*

× *Each person has different mathematical backgrounds and mathematical processing speeds so it is likely that this experiment would have a large amount of variability among subjects.*

× *The subject quickly started to use memory and different strategies that decreased the need for cognitive processing.*

Word Association (one-to-one)

- The subject is presented with a random word at the same time that they are presented with a cracker. They are instructed to say a word that is associated with the word they were presented with and do so before dropping the cracker into the cup. This is repeated 10 times, once for each cracker that is grasped. Time and cracker breaks are recorded. This same process was repeated but instead of open word association, the subject had to listen to the presented word and say the name of an animal beginning with the last letter of the presented word.

× *During the task, the subject is slowed by the same amount of time for both the NT and VPS hands.*

× *It is too easy for the subject to delay until the passing motion to say an associated word. This allows them to grasp the cracker and think at different times. It is such a quick task that delaying briefly until the grasp is over does not affect the speed.*

× *The presenter uses time saying the word, which affects the experiment because the time it takes to say the word is sometimes longer than the time it takes to move from dropping the cracker in the cup to grasping the next cracker. This skews the 1:1 ratio of words to cracker passes.*

× *With themed word association (animal names) the subject tends to repeat animals and learns how to use as little thought as possible. After this learning has happened, comparisons among trials that happened during the training period cannot be compared.*

Solve Short Definitions (one-to-one)

- The presenter says a two-word definition before the cracker is presented. The subject has to think of the term that the two words define and say it before dropping the next cracker in the cup (king's hat → crown). This is repeated 10 times, once for each cracker that is grasped. Time and cracker breaks are recorded.

× *There was very little delay in time due to the cognitive task.*

× *Again, there was the issue of the presenter delaying the task while speaking and the 1:1 ratio of definition to cracker pass tended to get skewed after 5 crackers because of this delay.*

× *It is difficult to force the subject to think while grasping the cracker. They tend to grasp the cracker and then think and complete the task during the transfer period between grasp and drop.*

✓ *The benefit of this method is that there is no strictly right or wrong answer. This facilitates thought without the same potential for performance anxiety that math problems may pose.*

Change Tense of Sentence (one-to-one)

- The presenter says a three word sentence before the cracker is presented. The subject has to change the tense of the sentence to past tense. The presented sentence can be in any tense, including past tense to start with.

This is repeated 10 times, once for each cracker that is grasped. Time and cracker breaks are recorded.

- ✓ *There was a higher delay percentage with the distraction when using the VPS hand than NT hand.*
- × *Again, there was the issue of the presenter delaying the task while speaking and the 1:1 ratio of definition to cracker pass tended to get skewed after 5 crackers because of this delay.*
- × *Repeated verbs allow the subject to work off of memory instead of thought.*
- × *It is difficult to force the subject to think while grasping the cracker. They tend to grasp the cracker and then think and complete the task during the transfer period between grasp and drop.*

Finger Tapping Rhythm (parallel)

- ✓ The subject performs the traditional unimanual cracker passing task with their prosthesis. During this task, they are instructed to continuously pinch their sound side thumb with each free finger, one after another, in a loop pattern starting with the pointer and ending with the pinky.
- × *Though the subject has to continuously think about which finger to tap, this is not a purely cognitive task – it is physical multi tasking.*
- × *This task did not significantly slow the subject with either prosthesis.*

Listen For Words in Story (parallel)

- During the traditional unimanual cracker passing task, the subject listens to a recorded story and is instructed to listen for a specific word (they, was, etc) and count the number of times it is repeated.
- × The subject found this task very difficult because once they got lost in the story or thought they missed one word, they gave up knowing they had already failed the task. This was deemed to be too difficult due to the fact that missing one word threw the subject off greatly.
- × The final number of words counted cannot be used as a metric for performance. Even if the person is listening intently, it is possible to over or under count. It is also possible for the person to make up a number at the end to avoid the task.
- ✓ A parallel task that does not involve a delay from the presenter dictating seems to be a good option. This kind of task requires constant attention whether grasping, transferring, or dropping the cracker.

Parallel Addition (parallel)

- During the traditional unimanual cracker passing task, the subject listens to a list of numbers that are dictated at regular intervals throughout the task. The numbers are small and are either positive or negative. The task is to add the numbers as they are presented throughout the passing task.
- × The subject found it difficult to continue once they became overwhelmed or missed a number.

× This task could be very difficult for someone who processes numbers slowly. It could also be very easy for someone who does this quickly and therefore the level of distraction is subjective.
✓ It was concluded that although a parallel task has its benefits, the task should not have a definitive answer at the end (no counting or math) because this leads to frustration.

Summarize Story (parallel)

- Throughout the unimanual grasping task, the subject summarizes a movie. This movie title is given to the subject just before the task starts and they are instructed to explain the plot as best possible using full sentences without pausing. No movie title is repeated.

✓ *Performance data showed that the subject did not get significantly worse using the NT hand during the distraction, however they did get significantly worse when using the VPS hand. The NT and sound side data was well correlated however it was obvious that the VPS hand took more effort.*
✓ *Due to the nature of "reliving" or recounting the plot of a story, it seems like the subject commits to the summary more than most verbal or mathematical tasks. The subject's interest in this type of task will keep them engaged and thinking.*
✓ *There is no right or wrong answer at the end of the task so it is easy for the subject to continue with little frustration.*
✓ *Any subject can complete this regardless of verbal or mathematical knowledge as long as they are provided with media titles they are familiar with.*
✓ *This encourages the person to think throughout the task without the ability to avoid thinking during the grasping phase.*
× *The quality of the summary varies among subjects, therefore their mental engagement in the task also varies.*
× *Able-bodied subjects may need a more difficult task to perform in a clinical setting in order to see a larger difference between the distracted and not distracted cases.*

<u>Outcome Measure Study Conduction</u>

- The final distraction methods were chosen and they are visual occlusion and cognitive distraction using story summarization. The outcome measure study procedure was refined, drafted, and tested. Documents for IRB protocol submission were created, submitted, and the study for evaluation with able-bodied individuals was approved as a minimal risk study. This includes the full procedure (Appendix B), modified procedure for a small subset of individuals to assess single and double handed performance (Appendix C), the study consent form and cover letter (Appendix D), and an exit questionnaire (Appendix E). This was then submitted for 2nd level military IRB and approved. Clinical protocol refinements were made in collaboration with CI Gary Berke and were approved by both IRB organizations. The conduction of the study has begun and 10/30 volunteers have performed the refined protocol. Preliminary data has been analyzed. It can be concluded

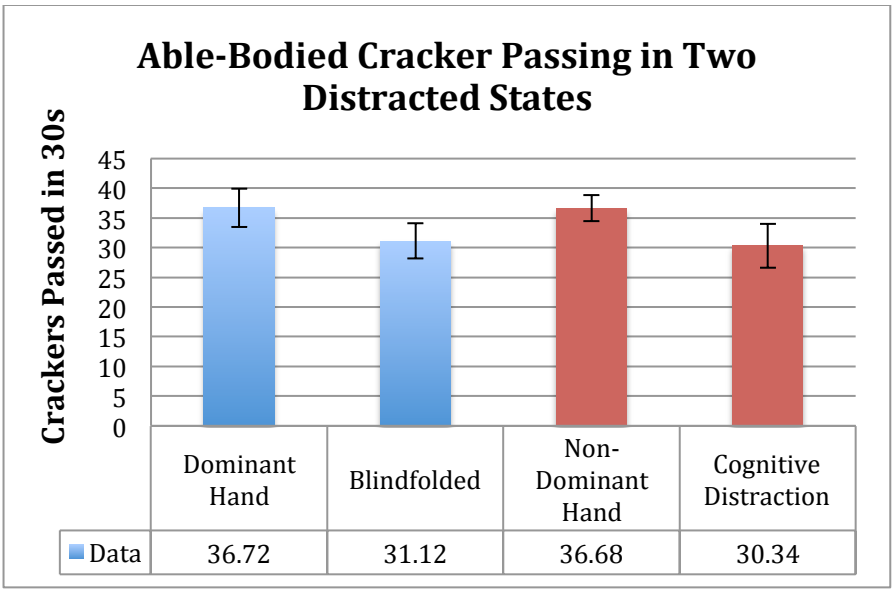
with statistical significance (P<0.05) that both distracted states are significantly slower than the corresponding non-distracted state. See data here:

Preliminary Outcome Measure Study Findings (10/30 Volunteers)

Four volunteers have performed the primary clinical study, which looks at the effect of both visual and cognitive distraction on fragile grasping performance in able-bodied subjects. The two distraction methods are performed using a bimanual grasping strategy. The visual distraction has the person perform the bimanual task, however they transfer the object between hands behind a curtain so the person cannot see. The cognitive distraction has the person summarizing a story as they perform the normal bimanual task. The volunteers also perform the bimanual tasks without any distraction so that we can compare to a baseline.

A two-way ANOVA test with repeated measures was implemented and it was found that both the testing condition (method of distraction) and trial-to-trial performance of individuals demonstrated significant differences (P<0.05). A post-hoc multiple comparisons test was performed via Tukey's multiple comparisons test to determine what conditions differed significantly. It was found that for the dominant hand, the blindfold and non-blindfolded cases differed significantly. It was also found that for the non-dominant hand, the distracted and non-distracted cases differed significantly. Additionally, the dominant non-blindfolded and non-dominant distracted cases differ significantly.

This study will continue until performance from 30 volunteers has been observed and analyzed.



Additional Work:

- An abstract and demonstration were submitted and included in the Haptics 2016 symposium, Philadelphia (Appendix F). The submission topic was about contact detecting sensors used on prosthetic hands and the contribution of this technology to fragile grasping tasks. This used data from visual occlusion outcome measure preliminary tests, which showed that the prosthetic hands with contact detecting sensors perform more similarly to able-bodied individuals than prosthetic hands without in both distracted and non-distracted states.
- An abstract has been submitted to AAOP 2017 (American Academy of Orthotists & Prosthetists) about our pre-study findings comparing bimanual fragile grasping of a myoelectric prosthesis user with and without the use of contact detecting sensors. The data is compared to that of able-bodied individuals performing the same task. The abstract is attached and is called "Contact Reflex Improves Fragile Grasping while Blindfolded."
- Steps have been made to prepare for the clinical study. SHAP (Southampton Hand Assessment Procedure) was ordered, evaluated, and determined not to be a useful outcome measure for use in clinical studies. CI Gary Berke finished ACMC training and some tasks have been tested using this assessment measure for inclusion in clinical studies. The Palo Alto VA has agreed to collaborate for the clinical study.

Major Task 4-1: Finalize experimental and research protocol, prepare regulatory documents, and recruit subjects for clinical studies

- Not yet begun

Major Task 4-2: Conduct clinical studies

- Not yet begun

Major Task 5-1: Prepare academic submissions and documentation

- Not yet begun

4) Other Accomplishments

What opportunities for training and professional development has the project provided?

- Nothing to report – the project was not intended to provide training and professional development apart from topic related conference attendance.

How were the results disseminated to communities of interest?

Nothing to Report

What do you plan to do during the next reporting period to accomplish the goals?

Nothing to Report

IMPACT:

What was the impact on the development of the principal discipline(s) of the project?

- The principal discipline of this project is related to the development or more advanced and useful prosthetic hands, improved contact detecting sensors, and outcome measures for the comparison of prosthetic hand utility. With this project, preliminary findings on the effects of visual and cognitive distractions have been presented to the public through both publication abstracts and project presentations (Haptics 2016, AAOP, ISPO).
- Distraction methods have been shown to affect fragile grasping performance in able-bodied individuals. We are therefore able to compare grasping performance of prosthesis users to able-bodied individuals in order to show how different types of prosthetic hands enable fragile grasping performance compared to the biological human hand. This comparison can be made without distracting stimuli and with visual or cognitive distractions in order to demonstrate the visual or cognitive focus someone may need to operate a particular type of prosthetic hand. This is likely to provide a new measure to determine how useful a particular prosthetic hand is in a more comprehensive way by comparing how much attention is needed to operate the hand.
- In addition to the aforementioned outcome measure development, this study is developing a smart prosthetic hand that includes contact detecting sensors in the fingers to improve fragile grasping abilities. It is anticipated and shown in preliminary studies that this prosthetic hand improves fragile grasping abilities for amputees and decreases the need for visual and cognitive attention compared to a standard prosthetic hand without sensors. It does not affect the ability to apply maximum force grasps. It is anticipated that this technology will improve the standard of prosthetic hands.

What was the impact on other disciplines?

Nothing to Report

What was the impact on technology transfer?

It is likely that the integration of sensing technology in prosthetic hands will prove effective enough that existing prosthetic hand companies will integrate the technology into their products. Additionally, it is anticipated that if the distraction method outcome measures are fully proven, they will be adopted as a new standard for the analysis of prosthetic hand utility by associated groups such as hand manufacturers, researchers, and prosthetists.

What was the impact on society beyond science and technology?

It is anticipated that the prosthetic hand technology that is being developed in this study will improve the fragile grasping abilities of upper limb amputees. They will be able to perform a wide variety of tasks that are otherwise very difficult. They will be able to perform these tasks with relatively low visual and cognitive focus, similarly to able-bodied individuals. This technology is anticipated to enable amputees and improve their confidence using their prosthetic hand.

CHANGES/PROBLEMS:

Changes in approach and reasons for change

Nothing to Report

Actual or anticipated problems or delays and actions or plans to resolve them

There has been an unanticipated delay in the production of the prosthetic hand finger sensors. It was determined that development of mechanical sensors would take longer than anticipated due to the cost and number of materials proposed. More time has been dedicated to preliminary prototyping, material research, and the designing of these sensors in order to produce sensors in a large batch instead of in stages. It was apparent early on that many potential designs could be eliminated by researching materials, performing material bench-top tests, and by researching materials. This approach is more financially and time efficient in the long-term plan of this project. Additionally, it was determined that more focus should be put on beginning the outcome measure study and electronic and firmware development so that all factors can be finished at the same time in preparation for the phase 2 study.

Additionally, it was apparent after testing the existing prosthetic finger sensors that a new finger core was necessary in order to improve the durability of the sensors. Time was allocated to the design and manufacturing of these new finger cores (using different designs) before they could be sent for foam molding.

Changes that had a significant impact on expenditures

We were able to perform material/treatment bench top tests in order to eliminate proposed material and treatment types. This cut down on the number of prototypes and cost of prototyping. At this time, only candidate materials and finger designs with a high anticipated probability of success are being sent for final manufacturing.

Significant changes in use or care of human subjects, vertebrate animals, biohazards, and/or select agents

Nothing to Report.

Significant changes in use or care of human subjects

Nothing to Report.

Significant changes in use or care of vertebrate animals.

Nothing to Report.

Significant changes in use of biohazards and/or select agents

Nothing to Report.

PRODUCTS:

Publications, conference papers, and presentations

Journal publications.

Nothing to Report.

Books or other non-periodical, one-time publications.

Nothing to Report.

Other publications, conference papers, and presentations.

- Muller, et al., "Tactile Sensing Reflex Reduces Need for Visual Feedback when Grasping Fragile Objects with a Prosthetic Hand," Haptics Symposium 2016.
    - Accepted symposium abstract. Federal support acknowledged.
- Berke, et al., "Contact Reflex Improves Fragile Grasping while Blindfolded," American Academy of Orthotists & Prosthetists 2017.

Website(s) or other Internet site(s)

Nothing to Report.

Technologies or techniques

Nothing to Report.

Inventions, patent applications, and/or licenses

Nothing to Report.

Other Products

- Prosthetic hand contact-detecting sensors for improvement in fragile object grasping and reduced cognitive load while being used by amputee.
- Work was done to develop and test clinical outcome measure for analysis of prosthetic hand utility with and without distractions. This measure is in development stages.

PARTICIPANTS & OTHER COLLABORATING ORGANIZATIONS

What individuals have worked on the project?

(1) Project Directors (PDs)/PIs

Name:	Jeremy Fishel
Project Role:	PI
Nearest person month worked:	8.5
Contribution to Project:	Dr. Fishel has coordinated all design review and project planning meetings to complete specific aims and worked alongside staff to ensure progress.

Name:	Gary Berke
Project Role:	CI
Nearest person month worked:	2.4
Contribution to Project:	Gary Berke has performed work planning future clinical studies, advising on outcome measure development, collecting data in outcome measure validation, and advising on the entire project.

Name: Ninad Karandikar
Project Role: Site PI, VA Palo Alto
Nearest person month worked: 0.4
Contribution to Project: Dr. Karandikar has met with CI and PI to discuss project schedule and has been exploring options to meet recruitment needs for future clinical studies and communicates with CI to coordinate future clinical studies recruitment and planning.

(2) Other Personnel (working more than 1 person month in reporting period)

Name: Blaine Matulevich
Project Role: R&D Manager
Nearest person month worked: 9
Contribution to Project: Mr. Matulevich has managed the development and evaluation of outcome measures and improvements to the mechanical and electrical design of the NumaTac sensors as well as the design of the controller electronics.

Name: Vikram Pandit
Project Role: Technician
Nearest person month worked: 3
Contribution to Project: Mr. Pandit has performed work in evaluating possible outcome measures to be developed and used in clinical studies. As an amputee himself he has provided critical feedback on the value of such tests in everyday prosthetic hand usage.

Name: Raymond Peck
Project Role: Mechanical Engineer
Nearest person month worked: 7.6
Contribution to Project: Mr. Peck has performed work related to the mechanical design and fabrication processes of the NumaTac sensors.

Name: Kelsey Muller
Project Role: R&D Engineer
Nearest person month worked: 10.3
Contribution to Project: Ms. Muller has performed work in developing and submitting IRB protocol and coordinating sensor evaluation and constructing test equipment.

Name: Rahman Davoodi
Project Role: Software and Firmware Engineer Advisor
Nearest person month worked: 1.8

Contribution to Project:	Dr. Davoodi has provided strategic advice on software and firmware for controller development in the early stages of the project.
Name:	Peter Botticelli
Project Role:	Production Engineer
Nearest person month worked:	2.1
Contribution to Project:	Mr. Botticelli has provided advisement on electronics design and manufacturing for the sensors and controller. He has also assisted with the development of testing equipment and had designed and manufactured electronics for this equipment.

Has there been a change in the active other support of the PD/PI(s) or senior/key personnel since the last reporting period?

Nothing to report.

What other organizations were involved as partners?

Organization Name: Berke Prosthetics
Location of Organization: Redwood City, California, USA
Partner's contribution to the project

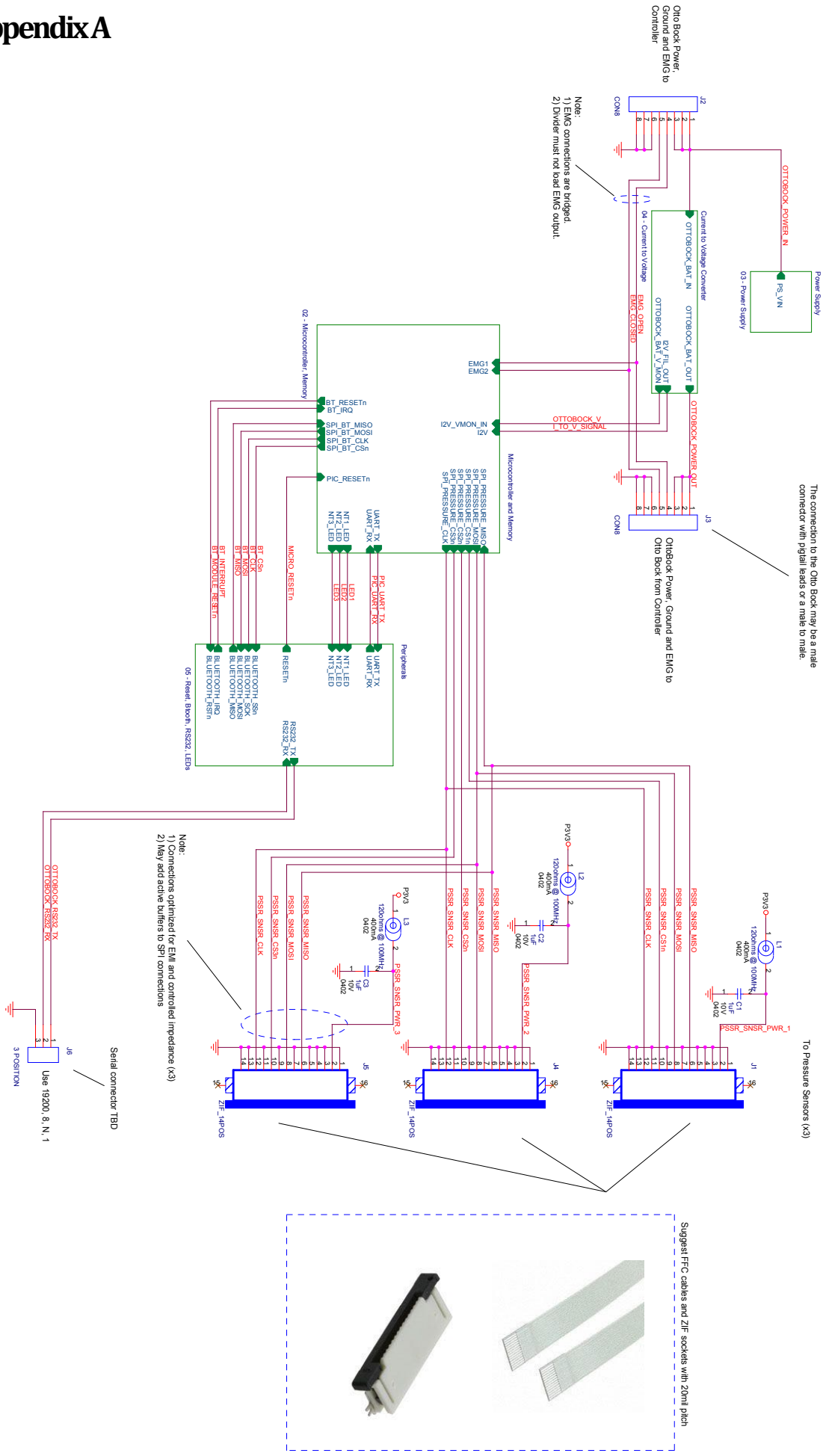
Financial support;
In-kind support: Partner advises on and conducts clinical studies. Partner also advises on outcome measure development
Facilities The partner's facilities are used for clinical study conduction.
Collaboration partner and partner's staff work on project.
Personnel exchanges SynTouch project staff may use the partner's facilities to aid with clinical study conduction.

SPECIAL REPORTING REQUIREMENTS

COLLABORATIVE AWARDS:
QUAD CHARTS:

APPENDICES:

Appendix A



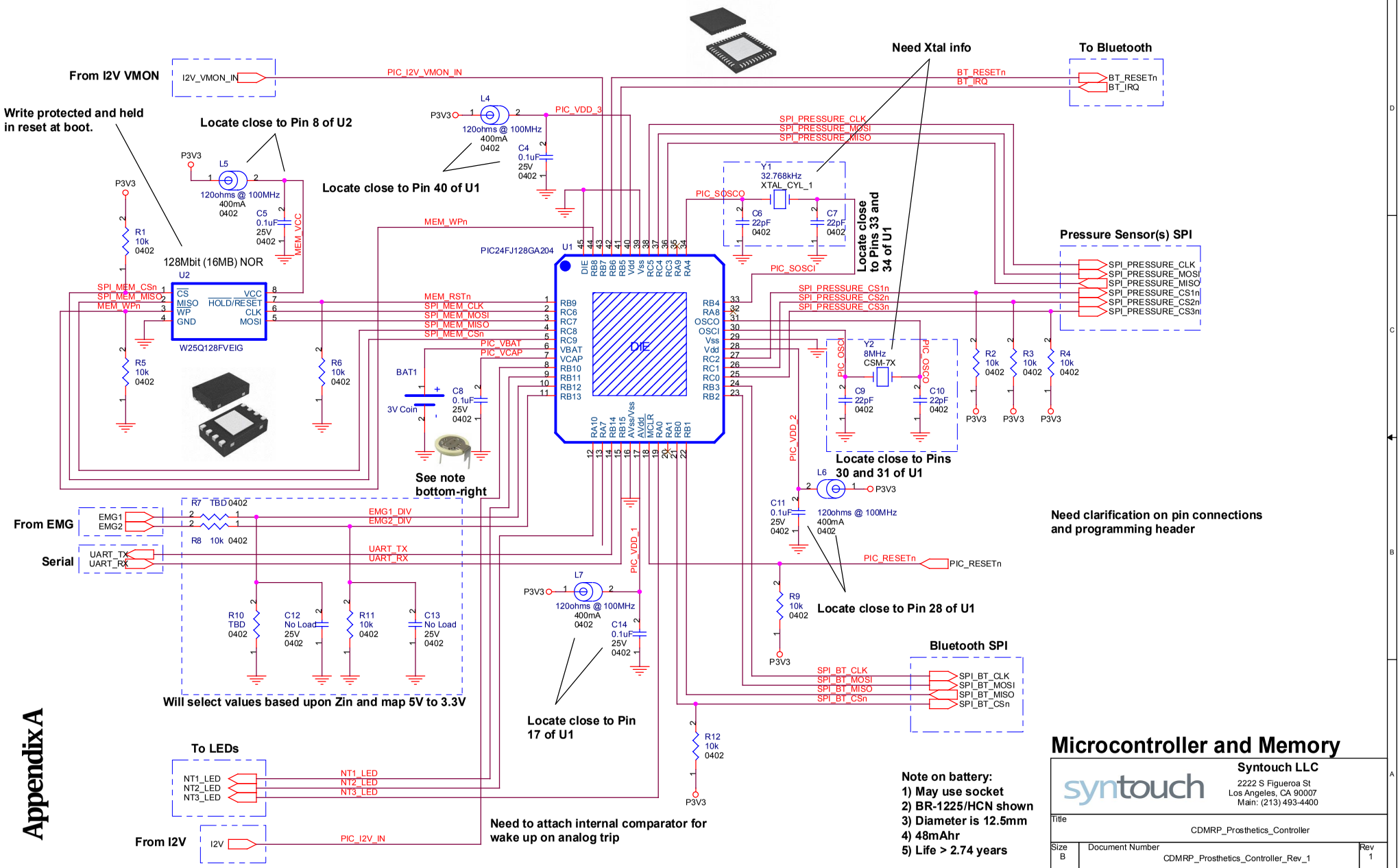
Top

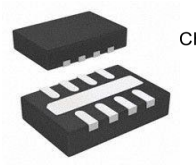
syntouch
Syntouch LLC
2222 S Figueroa St
Los Angeles, CA 90007
Main: (213) 483-4400

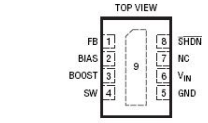
Size	Document Number	Rev
C	CDMRP_Prosthetics_Controller_Rev_1	1

Title: CDMRP_Prosthetics_Controller

Date: Friday, March 25, 2016 Sheet 1 of 6


From I2V VMON
I2V_VMON_IN
PIC_I2V_VMON_IN
Need Xtal info
To Bluetooth
BT_RESETn
BT_IRQ
Write protected and held in reset at boot.
Locate close to Pin 8 of U2
Locate close to Pin 40 of U1
P3V3
L4
120ohms @ 100MHz
400mA
0402
C4
0.1uF
25V
0402
PIC_VDD_3
L5
C5
0.1uF
25V
0402
MEM_VCC
R1
10k
0402
128Mbit (16MB) NOR
U2
W25Q128FVEIG
SPI_MEM_CSn
SPI_MEM_MISO
MEM_WPn
MEM_RSTn
SPI_MEM_CLK
SPI_MEM_MOSI
SPI_MEM_MISO
SPI_MEM_CSn
R5
10k
0402
R6
10k
0402
PIC24FJ128GA204
U1
DIE
PIC_VBAT
PIC_VCAP
BAT1
3V Coin
C8
0.1uF
25V
0402
See note bottom-right
SPI_PRESSURE_CLK
SPI_PRESSURE_MOSI
SPI_PRESSURE_MISO
Y1
32.768kHz
XTAL_CYL_1
PIC_SOSCO
PIC_SOSCI
C6
22pF
0402
C7
22pF
0402
Locate close to Pins 33 and 34 of U1
Pressure Sensor(s) SPI
SPI_PRESSURE_CS1n
SPI_PRESSURE_CS2n
SPI_PRESSURE_CS3n
Y2
8MHz
CSM-7X
C9
22pF
0402
C10
22pF
0402
R2
10k
0402
R3
10k
0402
R4
10k
0402
Locate close to Pins 30 and 31 of U1
PIC_VDD_2
L6
C11
0.1uF
25V
0402
120ohms @ 100MHz
400mA
0402
Need clarification on pin connections and programming header
From EMG
EMG1
EMG2
R7 TBD 0402
R8 10k 0402
EMG1_DIV
EMG2_DIV
Serial
UART_TX
UART_RX
PIC_RESETn
R9
10k
0402
Locate close to Pin 28 of U1
PIC_VDD_1
L7
120ohms @ 100MHz
400mA
0402
C14
0.1uF
25V
0402
R10
TBD
0402
C12
No Load
25V
0402
R11
10k
0402
C13
No Load
25V
0402
Will select values based upon Zin and map 5V to 3.3V
Bluetooth SPI
SPI_BT_CLK
SPI_BT_MOSI
SPI_BT_MISO
SPI_BT_CSn
Locate close to Pin 17 of U1
R12
10k
0402
To LEDs
NT1_LED
NT2_LED
NT3_LED
From I2V
I2V
PIC_I2V_IN
Need to attach internal comparator for wake up on analog trip
Note on battery:
1) May use socket
2) BR-1225/HCN shown
3) Diameter is 12.5mm
4) 48mAhr
5) Life > 2.74 years
Appendix A
Microcontroller and Memory
Syntouch LLC
2222 S Figueroa St
Los Angeles, CA 90007
Main: (213) 493-4400
Title
CDMRP_Prosthetics_Controller
Size B
Document Number
CDMRP_Prosthetics_Controller_Rev_1
Rev 1
Date: Friday, March 25, 2016
Sheet 2 of 6





DDB8 PACKAGE
8-LEAD (3mm × 2mm) PLASTIC DFN
θ_{JA} = 180°C/W
EXPOSED PAD (PIN 9) IS GROUND (MUST BE SOLDERED TO PCB)

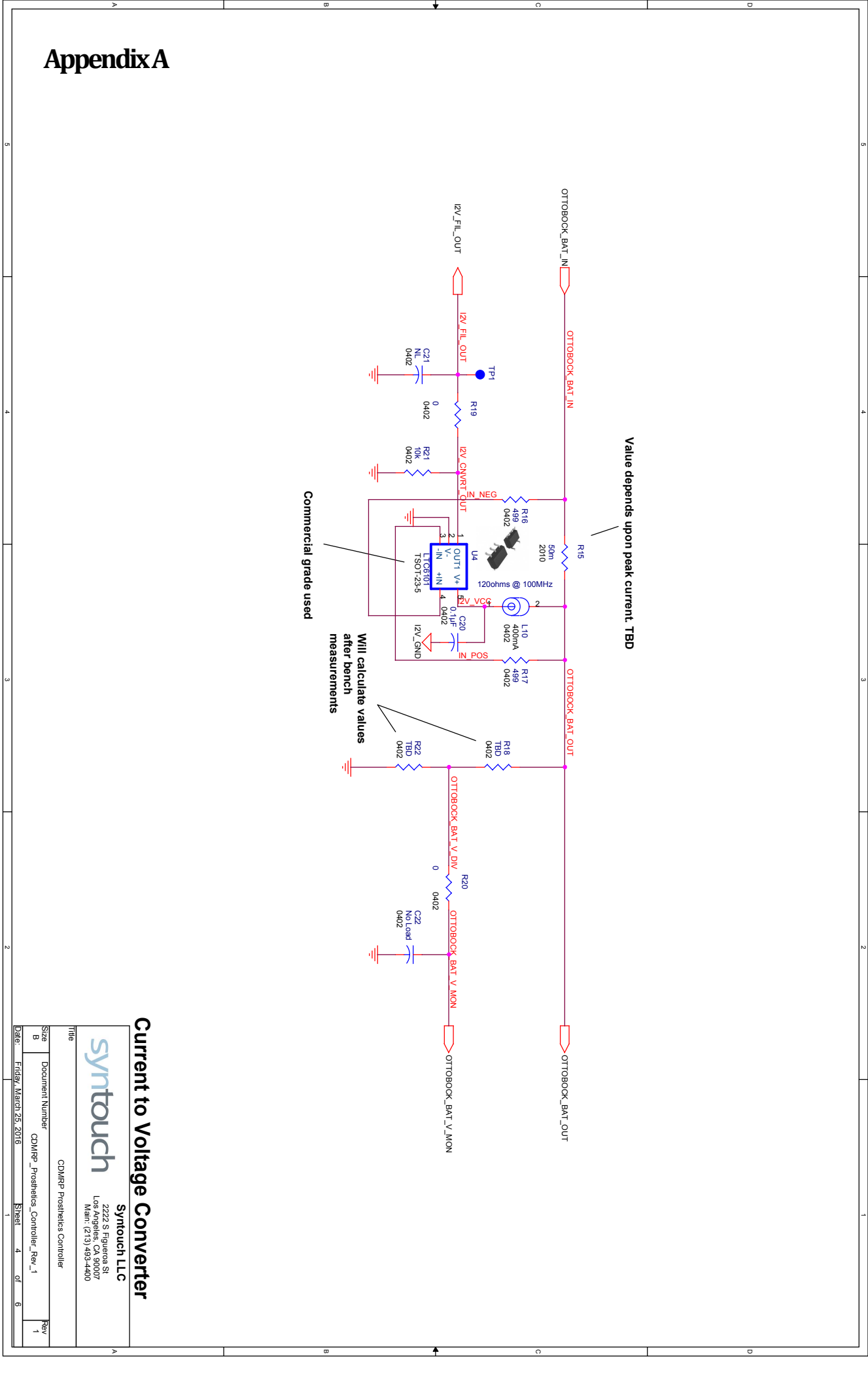
See Figure 5 of datasheet for PCB layout recommendations

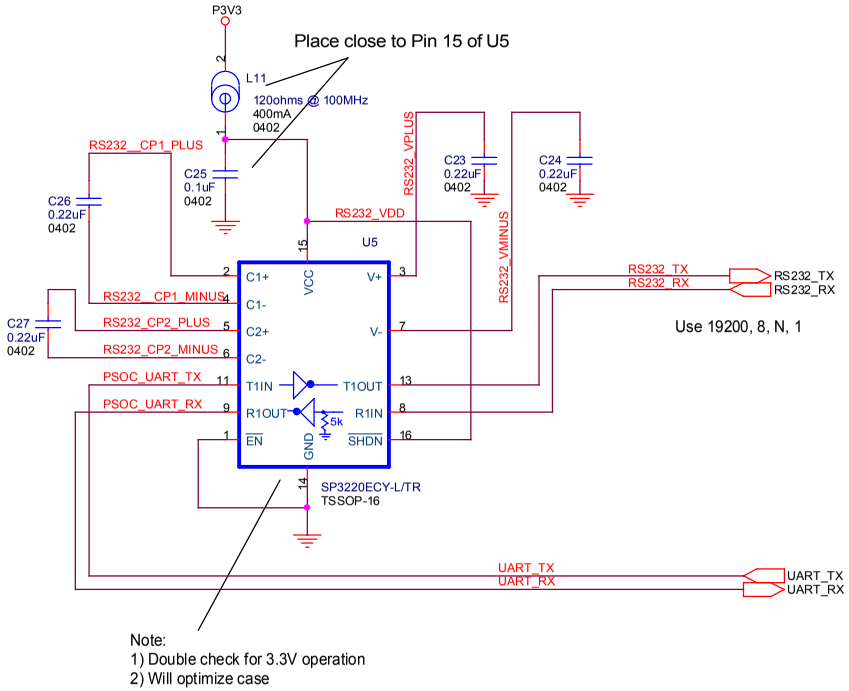
Appendix A

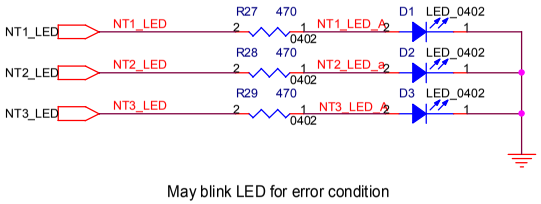
Power Supply

syntouch	**Syntouch LLC** 2222 S Figueroa St Los Angeles, CA 90007 Main: (213) 493-4400
Title	CDMRP_Prosthetics_Controller
Size: B	Document Number: CDMRP_Prosthetics_Controller_Rev_1 — Rev: 1
Date: Friday, March 25, 2016	Sheet 3 of 6

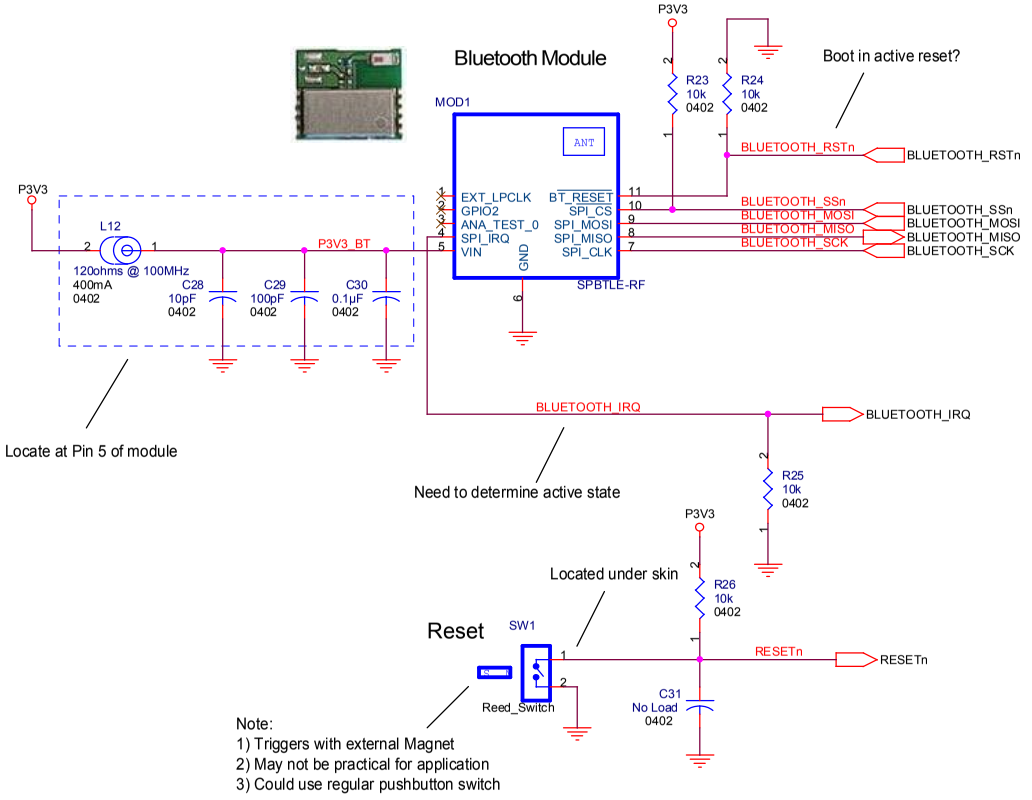
Appendix A


Current to Voltage Converter
Syntouch LLC
2222 S Figueroa St
Los Angeles, CA 90007
Main: (213) 493-4400
Title
CDMRP Prosthetics Controller
Size B
Document Number
CDMRP_Prosthetics_Controller_Rev_1
Rev 1
Date: Friday, March 25, 2016
Sheet 4 of 6
OTTOBOCK_BAT_IN
OTTOBOCK_BAT_OUT
OTTOBOCK_BAT_V_MON
I2V_FIL_OUT
I2V_CNVRT_OUT
I2V_VCC
I2V_GND
IN_NEG
IN_POS
OTTOBOCK_BAT_V_DIV
R15
50m
2010
R16
499
0402
R17
499
0402
R18
TBD
0402
R19
0
0402
R20
0
0402
R21
10k
0402
R22
TBD
0402
C20
0.1uF
0402
C21
NL
0402
C22
No Load
0402
L10
400mA
0402
120ohms @ 100MHz
U4
LTC6101
TSOT-23-5
OUT
V-
-IN
+IN
V+
TP1
Value depends upon peak current. TBD
Commercial grade used
Will calculate values after bench measurements





May blink LED for error condition

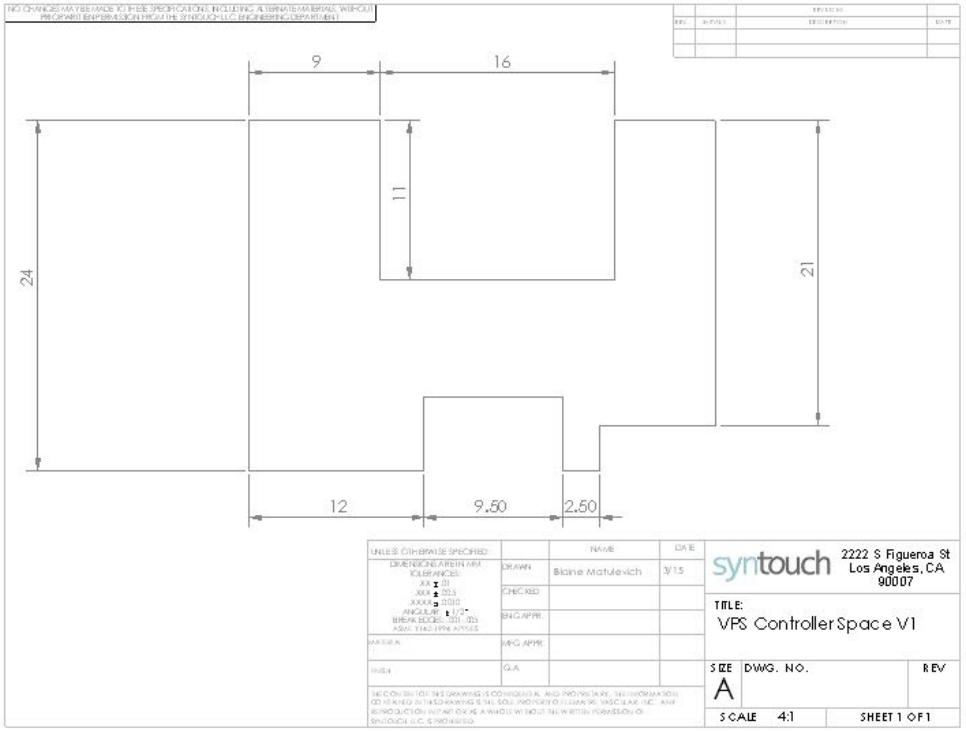


Appendix A

Reset, Bluetooth, Programmer, LEDs

syntouch	Syntouch LLC 2222 S Figueroa St Los Angeles, CA 90007 Main: (213) 493-4400	
Title	CDMRP Prosthetics Controller	
Size B	Document Number CDMRP_Prosthetics_Controller_Rev_1	Rev 1
Date: Friday, March 25, 2016	Sheet 5 of 6	

Preferred PCB outline



Appendix A

Mechanical

syntouch	Syntouch LLC 2222 S Figueroa St Los Angeles, CA 90007 Main: (213) 493-4400	
Title	CDMRP Prosthetics Controller	
Size B	Document Number CDMRP_Prosthetics_Controller_Rev_1	Rev 1
Date: Friday, March 25, 2016	Sheet 6 of 6	

Appendix B

Experimental Protocol – Full

1) Volunteer arrives at office for testing
2) Office obtains a signed consent form if not already on file
3) Volunteer is given a list of movies and instructed to indicate which, if any, they are familiar enough with to verbally summarize for a span of about 30 seconds. Volunteer is also given a blank list to fill in with additional movies if they could not circle 20 on the previous list.
4) Audio and video recording device is started and the experimenter states the participant's ID number, date, dominant hand, and time of recording. They then ask the participant "are you aware you are being audio and video recorded during this session? Do we have your permission to record and video this session?"
5) Volunteer is given a brief verbal overview of the background and purpose of the study. This will include the fact that we're testing two different outcome measures with healthy individuals and that this info will be used in a future study on the effectiveness of prosthetic hands.
6) Volunteer is given a brief introduction to the bimanual passing procedure and allowed to practice the task. Volunteer will then be given a brief introduction to the cognitive distraction and blindfold procedures and allowed to practice if desired.
7) The participant is instructed to follow the grasping task procedure according to the table on the last page. The table outlines the flow that should be followed and includes combinations of the bimanual passing task, handedness (left or right), blindfolding procedure, and distraction procedure. These procedures can be found below.
    a. Bimanual Passing Task
        i. Volunteer is standing facing a table with a centerline directly in front of them, a line 18" to their left, and a line 18" to their right.
        ii. Volunteer indicates when they are ready to begin the timed portion.
        iii. Researcher presents two trays of crackers for the volunteer to receive from at one line. The volunteer will remove crackers from the tray that corresponds to the hand they are grasping with (ie. receive with left hand, start with left tray). They cannot move on to the next tray until the previous is finished. The researcher will replace the empty tray when the volunteer has moved on to the next.
        iv. Volunteer starts with two hands on the table. When the timer starts, it will beep, indicating that they can grasp the first cracker with their hand.
        v. Volunteer passes object to their other hand.
        vi. Volunteer moves cracker to the cup, located on the 18" line opposite the receiving line, without breaking or dropping it.
        vii. Volunteer releases the object in the cup. It is important that the person attempts to drop the cracker in the cup but perfection is not necessary.
        viii. Steps c-f are repeated until 30 seconds have elapsed. No additional crackers can count towards the total after 30 seconds have elapsed.
        ix. The number of intact objects that were placed in the predetermined location is recorded.

Appendix B

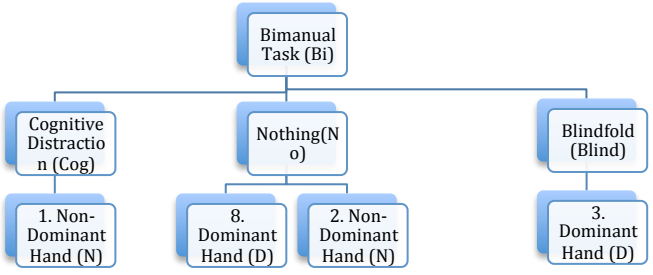
x. Volunteer is allowed to rest until they indicate they are ready to begin again.
xi. Researcher may re-instruct the volunteer on the protocol if performed improperly.

b. Blindfold
   i. The individual has a blindfold curtain in front of them while standing at the table.
   ii. The individual performs the bimanual grasping task and transfers the cracker to their other hand behind the curtain. They may not see the transfer. Touching the curtain is allowed as long as this does not allow them to see their hands. They may see the cracker when grasping it and when dropping it in the cup.

c. Distraction
   i. Presenter will say the name of one media source written or chosen by the volunteer on the entry media survey. It is dictated that the goal is to talk about the movie and convey the plot using full sentences without pausing or repeating the movie title (i.e. "The movie Shrek is about..."). The volunteer will begin speaking when the timer starts and can stop when the timer stops. They cannot pause or delay dictation for more than 2 seconds. A unique media title is used for each trial and if there is a mistake during the trial, a new media title needs to be used. Tell the person to avoid just saying single words or pausing, they should try to speak continuously even if they're giving their opinion about the movie or talking about just one scene. This procedure can be performed during bimanual or unimanual tasks.

d. Handedness
   i. A left hand trial means that the left hand is used to receive the cracker. A right hand trial means the right hand is used to receive the cracker. For the bimanual task, the individual will receive with one hand and place the cracker in the cup with the other hand.

8) Volunteer will perform the following combinations of tasks in order until 5 trials of each combination have been performed.
9) Volunteer be given an exit survey about their experience.
10) Audio and video recording is stopped.



	Task Combination			
Repetition	1	2	3	4
1	Bi, Cog, N	Bi, No, D	Bi, Blind, N	Bi, No, D
2	Bi, Cog, N	Bi, No, D	Bi, Blind, N	Bi, No, D
3	Bi, Cog, N	Bi, No, D	Bi, Blind, N	Bi, No, D
4	Bi, Cog, N	Bi, No, D	Bi, Blind, N	Bi, No, D
5	Bi, Cog, N	Bi, No, D	Bi, Blind, N	Bi, No, D

Appendix C

Experimental Protocol – Subgroup

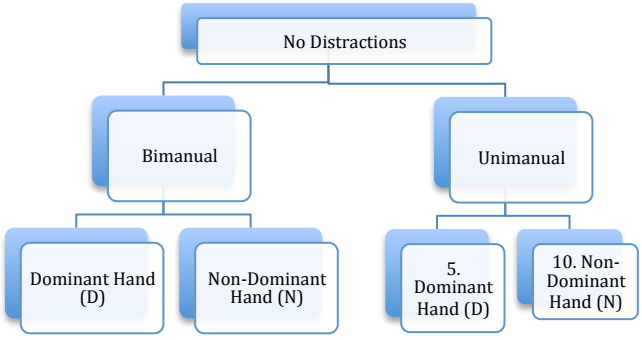
1) Volunteer arrives at office for testing
2) Office obtains a signed consent form if not already on file
3) Audio and video recording device is started and the experimenter states the participant's ID number, date, dominant hand, and time of recording. They then ask the participant "are you aware you are being audio and video recorded during this session? Do we have your permission to record and video this session?"
4) Volunteer is given a brief verbal overview of the background and purpose of the study. This will include the fact that we're testing two different outcome measures with healthy individuals and that this info will be used in a future study on the effectiveness of prosthetic hands.
5) Volunteer is given a brief introduction to the bimanual and unimanual experiment and allowed to practice the tasks.
6) The participant is instructed to follow the grasping task procedure according to the table on the last page. The table outlines the flow that should be followed and includes combinations of the unimanual passing task, bimanual passing task, and handedness (left or right). These procedures can be found below.
    a. Bimanual Passing Task
        i. Volunteer is standing facing a table with a centerline directly in front of them, a line 18" to their left, and a line 18" to their right.
        ii. Volunteer indicates when they are ready to begin the timed portion.
        iii. Researcher presents two trays of crackers for the volunteer to receive from at one line. The volunteer will remove crackers from the tray that corresponds to the hand they are grasping with (ie. receive with left hand, start with left tray). They cannot move on to the next tray until the previous is finished. The researcher will replace the empty tray when the volunteer has moved on to the next.
        iv. Volunteer starts with two hands on the table. When the timer starts, it will beep, indicating that they can grasp the first cracker with their hand.
        v. Volunteer passes object to their other hand.
        vi. Volunteer moves cracker to the cup, located on the 18" line opposite the receiving line, without breaking or dropping it.
        vii. Volunteer releases the object in the cup. It is important that the person attempts to drop the cracker in the cup but perfection is not necessary.
        viii. Steps c-f are repeated until 30 seconds have elapsed. No additional crackers can count towards the total after 30 seconds have elapsed.
        ix. The number of intact objects that were placed in the predetermined location is recorded.
        x. Volunteer is allowed to rest until they indicate they are ready to begin again.
        xi. Researcher may re-instruct the volunteer on the protocol if performed improperly.
    b. Unimanual Passing Task

Appendix C

i. Volunteer is standing facing a table with a centerline directly in front of them, a line 18" to their left, and a line 18" to their right.
ii. Volunteer indicates when they are ready to begin the timed portion.
iii. Researcher presents two trays of crackers for the volunteer to receive from at one line. The volunteer will remove crackers from the tray that corresponds to the hand they are grasping with (ie. receive with left hand, start with left tray). They cannot move on to the next tray until the previous is finished. The researcher will replace the empty tray when the volunteer has moved on to the next.
iv. Volunteer starts with two hands on the table. When the timer starts, it will beep, indicating that they can grasp the first cracker with their hand.
v. Volunteer moves cracker to the cup, located on the far-side line, without breaking or dropping it.
vi. Volunteer releases the object in the cup. It is important that the person attempts to drop the cracker in the cup but perfection is not necessary.
vii. Steps c-f are repeated until 30 seconds have elapsed. No additional crackers can count towards the total after 30 seconds have elapsed.
viii. The number of intact objects that were placed in the predetermined location is recorded.
ix. Volunteer is allowed to rest until they indicate they are ready to begin again.
x. Researcher may re-instruct the volunteer on the protocol if performed improperly.

c. Handedness
   i. A left hand trial means that the left hand is used to receive the cracker. A right hand trial means the right hand is used to receive the cracker. For the bimanual task, the individual will receive with one hand and place the cracker in the cup with the other hand. For the unimanual task, the individual will receive and place the cracker with one hand.

7) Volunteer will perform the following combinations of tasks in order until 5 trials of each combination have been performed.
8) Audio and video recording is stopped.



	Task Combination			
Repetition	1	2	3	4
1	Bi, D	Bi, N	Uni, D	Uni, N
2	Bi, D	Bi, N	Uni, D	Uni, N
3	Bi, D	Bi, N	Uni, D	Uni, N
4	Bi, D	Bi, N	Uni, D	Uni, N
5	Bi, D	Bi, N	Uni, D	Uni, N

Appendix D

syntouch

2222 South Figueroa St. PH2
Los Angeles, CA 90007
Phone: (213) 493-4400
E-Mail: info@syntouchLLC.com
Web: www.syntouchLLC.com

Dear Potential Volunteer,

You are invited to participate in our research to evaluate the effects of distraction on grasping objects. The results of this study will be used to develop new ways to assess next-generation prosthetic hands. Though it will not have direct or immediate benefits for you, this research will assist in the development and evaluation of prosthetic hands that may benefit the amputee community.

Please review the attached document carefully. It outlines both the benefits to society and risks to you if you choose to participate in this research. Please know that if you agree to participate, or do not agree to participate it will not alter or affect your relationship with SynTouch, Berke Prosthetics, or any other entity involved in this study. Also please know if you agree to participate, you may change your mind or withdraw from the study at any point prior to or during the research without penalty. Additionally, there is a video and audio recording component of this study used for data analysis. Information gathered from the recordings may be used in printed research such as articles and confidentiality will be preserved.

If after reviewing the description of the research study you have any questions, please contact the researchers directly using the contact information provided below.

Thank you for your consideration of this request for participation.

Sincerely,

Jeremy A. Fishel
Principal Investigator
SynTouch, LLC
office: (213) 493-4400
email: Jeremy.Fishel@SynTouchLLC.com

Gary Berke
Principal Investigator
Berke Prosthetics
office: (650) 365-5861
email: GBerke@BerkeProsthetics.com

Appendix D

VALIDATION OF GRASPING OUTCOME MEASURES

INFORMATION AND CONSENT FORM

Introduction:
You are invited to participate in our research to evaluate the effects of distraction on grasping objects. The results of this study will be used to develop new ways to assess next-generation prosthetic hands. This DOD funded study is being conducted by Jeremy Fishel of SynTouch, LLC and Gary Berke at Berke Prosthetics in Redwood City, CA. You have been selected as a possible participant in this research because you are a healthy adult able to perform grasping tasks with both hands. Please read this form and ask questions before you agree to participate in the study, which can be directed to either Jeremy Fishel or Gary Berke (contact information below).

Background Information:
The purpose of this study is to assess how you perform when grasping fragile objects with and without visual distraction (blindfolded or not) and with and without cognitive distraction (while talking or not). Thirty people are expected to participate in this research study.

Procedures:
If you decide to participate, you will be asked to perform the following tasks:

1) You will complete a questionnaire asking you to indicate what media sources you are familiar with and able to describe (movies, TV shows, books, etc.) or write down alternative titles from such sources (5 minutes).
2) You will be informed of the testing procedures of the tasks and allowed to practice these tasks. You will be asked if you consent to the test being video and audio recorded (5 minutes).
3) Each task will be completed and timed before moving on to the next task. You will cycle through the 4 tasks several times starting with the indicated hand, left or right. You will be allowed to rest in between each trial if desired (25-45 minutes total).
    a. Task 1: While standing, the researcher will present trays of fragile objects for you to grasp with one, pass to your other hand, and drop in a predetermined location. The total amount of unbroken objects passed in 30 seconds will be recorded.
    b. Task 2: The same as Task 1, but without the ability to see your hands.
    c. Task 3: The same as Task 1, but while summarizing a form of media (movie, book, etc.).
    d. Task 4: The same as Task 1, but passing in the opposite direction.
4) You will fill out an exit questionnaire about your experience.

This study will take approximately 40-60 minutes total. The audio and video recording component of this study is done to aid in data analysis, which may be reported in print research.

Risks and Benefits of being in the study:
The study has minimal risks. First, you may experience fatigue however, the likelihood of this risk is low if you do not experience this type of fatigue while using your hands for periods over 60 minutes. Second, while we will make every effort to ensure your participation in the study is kept confidential as required by protocol, there is always a risk that it may be accidentally disclosed unintentionally. Recordings will only be used by researchers and destroyed following the analysis of data. If you have any concerns with these risks it is advised that you discuss with the researchers before signing this consent form or participating in the study. If at any point during the study you appear to be in discomfort or unable to safely conduct the remainder of the study, the researchers will end the study.

There will be no direct benefits to you for participating in this research. Your participation is completely voluntary and if you decide not to participate, your relationships with Berke Prosthetics, SynTouch LLC, or any other entity involved in this study will not change in any way.

Compensation:

Appendix D

If you participate in this study, you will need to travel to Redwood City and you will receive $25 as compensation for your time and inconvenience of travel.

In the event that your participation in this research activity results in an injury, we will be unable to provide any compensation. Any medical care for research-related injuries should be paid by you or your insurance company. If you think you have suffered a research-related injury, please, inform the researchers as soon as possible so they can notify appropriate safety review boards.

Confidentiality:
Any information obtained in connection with this research study that can be identified with you will be disclosed only with your permission; your individual results will be kept confidential. In any media, written reports or publications, no one will be identified or identifiable and only group data will be presented.

The researchers will maintain all research results and records in locked file cabinets at offices of SynTouch and Berke Prosthetics. Only the researchers at these institutions will have access to the records while analyses of results are performed for this research project. The department of defense (DOD) or Federal representatives may access research records for the purpose of protecting human subjects.

Voluntary nature of the study:
Participation in this research study is voluntary. Your decision whether or not to participate will not affect your future relations with Berke Prosthetics, SynTouch LLC, or any other entity involved in this study in any way. If you decide to participate, you are free to stop at any time without affecting these relationships.

Contacts and questions:
If you have any questions, please feel free to contact the researchers:
Gary Berke, Berke Prosthetics – GBerke@BerkeProsthetics.com, phone: 650-365-5861.
Jeremy Fishel, SynTouch – email: Jeremy.Fishel@SynTouchLLC.com, phone: 213-493-4400

You may ask questions now, or if you have any additional questions later, the researchers will be happy to answer them. If you are interested in participating, please notify the above researchers for additional information.

This project has been reviewed and approved by the Heartland Institutional Review Board. Questions concerning your rights as a participant in this research may be addressed to the Executive Director at Heartland IRB. Office: (866) 618-HIRB; Fax: (866) 300-0679; or by emailing director@heartlandirb.org.

Please, keep one copy of this letter and consent form for your records and return the other signed copy to the researcher/s.

Thank you,

Jeremy Fishel / Gary Berke
213-493-4400/ 650-365-5861

Statement of Consent

You are making a decision whether or not to participate.
Select whether you agree to participate or choose not to participate.
Your signature indicates that you have read this information and your questions have been answered.
Even after signing this form, please know that you may withdraw from the study at any time.

Appendix D

___ I consent to participate in the study.

___ I do NOT consent to participate in this study.

_____

Participant name (please, print)

_____

Signature of Participant Date

Video and Recording Consent

You are making a decision whether or not to give permission for the video and audio recording of this experiment.
Select whether you agree to be videoed and recorded in this experiment.
Even after signing this form, please know that you may withdraw from the study at any time.

___ I agree to have my session video and audio recorded and understand that I may withdraw my consent at any time without penalty.

___ I do NOT agree to have my session video or audio recorded

_____

Signature of Participant Date

English:

This project has been reviewed and approved by the Heartland Institutional Review Board. Questions concerning your rights as a participant in this research may be addressed to the Executive Director at Heartland IRB. Office: (866) 618-HIRB; Fax: (866) 300-0679; or by emailing director@heartlandirb.org.

Spanish:

Este proyecto ha sido revisado y aprobado por Heartland Institutional Review Board. Preguntas sobre sus derechos como participante en esta investigación pueden dirigirse al Directo Ejecutivo de Heartland IRB. Oficina: (866) 618-HIRB; Fax: (866) 300-0679; o por correo electrónico: director@heartlandirb.org.

Appendix E

Exit Questionnaire

Please indicate how you felt you performed in each of the following categories by filling in the appropriate box. Optional comments can be written to the right.

Example: How easy was it to pass the object to yourself?

No Blindfold:

Blindfolded:

Didn't notice a huge difference

1. How physically demanding was the task?

No Blindfold:

Blindfolded:

2. How distracted were you during the task?

No Blindfold:

Blindfolded:

3. How frustrated were you during the task?

No Blindfold:

Blindfolded:

4. How successful were you in accomplishing what you were asked to do?

No Blindfold:

Blindfolded:

5. How hard did you have to work to accomplish your level of performance?

No Blindfold:

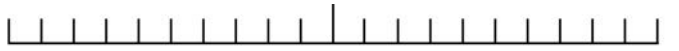
Blindfolded:

Appendix E

Please indicate how you felt you performed in each of the following categories by filling in the appropriate box. Optional comments can be written to the right.

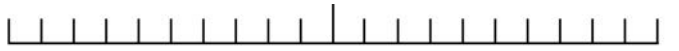
1. How physically demanding was the task?

No Distraction:



Not Demanding Very Demanding

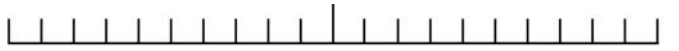
Distracted:



Not Demanding Very Demanding

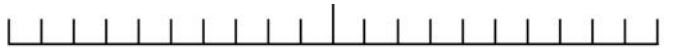
2. How distracted were you during the task?

No Distraction:



Not Distracted Very Distracted

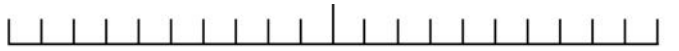
Distracted:



Not Distracted Very Distracted

3. How frustrated were you during the task?

No Distraction:



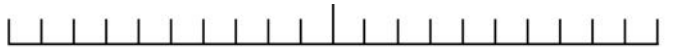
Not Frustrated Very Frustrated

Distracted:

Not Frustrated Very Frustrated

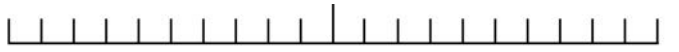
4. How successful were you in accomplishing what you were asked to do?

No Distraction:



Successful Not Successful

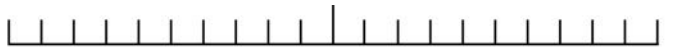
Distracted:



Successful Not Successful

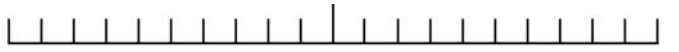
5. How hard did you have to work to accomplish your level of performance?

No Distraction:



Not Hard Very Hard

Distracted:



Not Hard Very Hard

English: This project has been reviewed and approved by the Heartland Institutional Review Board. Questions concerning your rights as a participant in this research may be addressed to the Executive Director at Heartland IRB. Office: (866) 618-HIRB [4472]; Fax: (866) 414-0517; or by emailing director@heartlandirb.org.

Spanish: Este proyecto ha sido revisado y aprobado por Heartland Institutional Review Board. Preguntas sobre sus derechos como participante en esta investigación pueden dirigirse al Directo Ejecutivo de Heartland IRB. Oficina: (866) 618-HIRB [4472]; Fax: (866) 414-0517; o por correo electrónico: director@heartlandirb.org.

Appendix F

Tactile Sensing Reflex Reduces Need for Visual Feedback when Grasping Fragile Objects with a Prosthetic Hand

Kelsey A. Muller, Vikram Pandit, Blaine Matulevich, Jeremy A. Fishel, *Member, IEEE*

***Abstract*— Able-bodied individuals can perform complex manipulation tasks without looking because of their ability to feel. Amputees utilizing a myoelectric prosthetic hand without the ability to feel need to compensate with visual feedback to help control grasping forces. In this study, a standard myoelectric prosthetic hand is equipped with compliant tactile sensors and an autonomous contact detection reflex to simplify grasping and reduce the user's reliance on vision. A single unilateral amputee and prosthesis user's performance was evaluated in a fragile grasping task between this modified prosthesis and an unmodified prosthesis. This was done with and without visual occlusion. Additionally, performance with and without visual occlusion is evaluated for three able-bodied subjects. In all scenarios, it was found that the occlusion of vision slowed the performance of the test subject, however, performance with the modified prosthesis was only slightly degraded (16.1%) with vision occluded, similar to able-bodied subjects (21.2%), but significantly hindered with the unmodified prosthesis (80.1%). Furthermore, it was found that the amputee subject could perform the grasping task faster without vision using the modified prosthesis than using the unmodified prosthesis unobstructed. This technology is expected to improve a user's confidence and decrease the visual attention needed when using a myoelectric prosthetic hand.**

I. INTRODUCTION

In the human hand, tactile feedback plays a critical role in object grasping and manipulation [1]. This allows able-bodied individuals to divert visual attention when grasping, which facilitates multitasking and grasping without visual focus (e.g. putting on clothes or picking up a glass while reading). For a myoelectric prosthesis user, surface electromyography (EMG) signals are recorded from the residual limb to provide control signals to a prosthetic hand, typically driven by DC electric motors. When these hands close on an object, the motors stall, typically producing large grasping forces unless visual feedback is used to control the closing speed and stopping time of the hand. Reducing the visual attention required to operate a myoelectric prosthesis would greatly improve the utility of these devices.

One approach to this utilizes a tactile grasping reflex that detects when the prosthetic fingers close on an object and adjusts the control of the prosthesis [2]. In this work, a highly sensitive and compliant tactile sensor (the NumaTac, SynTouch, Los Angeles) was integrated into a prosthetic hand (Figure 1). Mechanical integration was achieved by replacing an original finger with the NumaTac finger, and electronic integration by intercepting communication between the EMG electrodes and prosthetic hand motors and modifying these signals based on sensor data. When contact is detected by the sensor during a grasp, the gain of the controlling EMG signals is reduced, a process similar to a natural spinal inhibitory reflex. This has been demonstrated to greatly improve speed and accuracy when grasping fragile objects.

Figure 1. A) Custom NumaTac prosthetic fingertip sensor core and foam; B) Ottobock VariPlus Speed hand installed with two NumaTac fingers, a thumb, and electronics.

The more difficult a dexterous task, the more visual attention is required; therefore, it is expected that hand performance without visual feedback is reflective of the utility of the hand [3, 4]. In this study we observed speed and accuracy during bimanual fragile grasping tasks in two situations: full vision and while blindfolded to simulate visual occlusion (Figure 2). The NumaTac-sensorized VariPlus Speed hand (NT) performance is compared to that of the same hand without contact detecting reflexes (VPS).

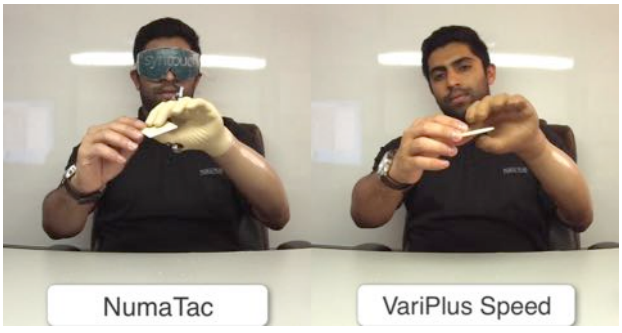


Figure 2. Two examples of the fragile cracker grasping task using 1) the NumaTac sensorized hand while blindfolded and 2) the unsensorized VariPlus Speed Hand with full vision.

* This work was supported by the Office of the Assistant Secretary of Defense for Health Affairs through the Clinical and Rehabilitative Medicine Research Program under Award No. W81XWH-15-1-0149. Opinions, interpretations, conclusions and recommendations are those of the author and are not necessarily endorsed by the Department of Defense.

K. A. Muller is with SynTouch LLC, Los Angeles, CA (corresponding author, e-mail: kelsey.muller@syntouchllc.com).

V. Pandit is with SynTouch LLC, Los Angeles, CA (e-mail: vikram.pandit@syntouchllc.com).

B. Matulevich is with SynTouch LLC, Los Angeles, CA (e-mail: blaine.matulevich@syntouchllc.com).

J. A. Fishel is with SynTouch LLC, Los Angeles, CA (e-mail: jeremy.fishel@syntouchllc.com).

Appendix F

Performance is also compared to able-bodied individuals as a baseline to understand the role of vision in this task.

II. METHODS

As a fragile grasping task, the amputee subject (second author VP) was asked to pick up a fragile object (saltine cracker) from the table top with their sound-side hand, pass it to their prosthetic hand (Figure 2) without breaking the object, and place it into a cup. This was repeated ten times as quickly as possible, with broken objects being replaced. Five trials were recorded to find average task speed and the experiment was repeated under two test conditions:

1. *Full vision – subject had no visual obstruction.*
2. *No vision – subject was completely blindfolded.*

Performance was tested with one subject, a 23-year-old male, congenital, unilateral, transradial amputee and regular myoelectric prosthesis user. Each scenario was performed using an unmodified Ottobock VariPlus Speed (VPS) and an Ottobock VariPlus Speed hand equipped with NumaTacs and a contact detection reflex (NT). As a control, three able-bodied individuals between the ages of 25-27 followed the aforementioned protocol using both sound hands. Data were averaged to obtain task speed and accuracy of bimanual passing between able-bodied subjects (AB) for each visual condition. Control and test subjects were allowed to practice under each condition until steady performance was achieved.

III. RESULTS

In all scenarios for the prosthesis user, bimanual passing with the NT hand was found to be significantly faster and showed fewer grasping failures than with the unmodified VPS hand (Table 1). In addition, the blindfold hampered the VPS task speed significantly more than either the NT or AB hands (Figure 3). The blindfold slowed AB speed by an average of 2.2 seconds, NT by 2.7 seconds, and VPS by 18.2 seconds.

TABLE I. DATA SUMMARY

	Able-Bodied	NumaTac	VPS
Vision			
Time (s)	10.4	16.8	22.5
Breaks	0	0.2	1
Blindfold			
Time (s)	12.6	19.5	40.7
Breaks	0	0.2	0.4
Comparison			
Delay due to Blindfold	2.2	2.7	18.2
% Worse with Blindfold	21.2%	16.1%	80.1 %

IV. DISCUSSION

Myoelectric prostheses with contact detecting sensors and biomimetic reflexes have been demonstrated to improve the speed and accuracy of bimanual, fragile grasping tasks when compared to the same hand without this technology. Gratifyingly, fragile grasping with the NT hand was so efficient that the subject could perform the task faster without vision with this hand than with vision and the unsensorized prosthesis.

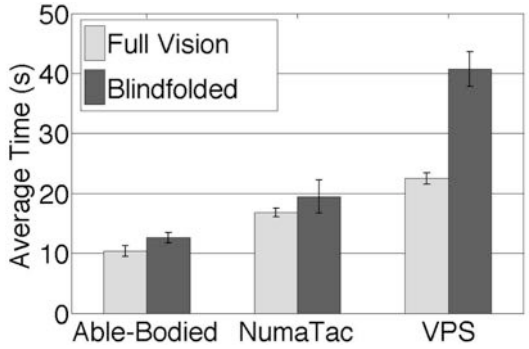


Figure 3. Average bimanual task performance speeds for each hand with full vision and while blindfolded. Hand types include able-bodied (AB), NumaTac sensorized (NT), and unsensorized VariPlus Speed Hand (VPS).

When vision is removed, the NT hand showed a delay in speed similar to able-bodied subjects, indicating that the reflexive behavior restores some of the capability and autonomy of natural hands while grasping fragile objects. Meanwhile, the task speed with the VPS hand is substantially more degraded when vision is removed. This makes it apparent that use of the unsensorized hand relies heavily on visual feedback. With contact detection, grasping is quicker and more natural because, just like with a sound hand, vision can be averted without greatly compromising performance. This is desired when using a prosthesis for functional, every-day tasks. This is because a prosthesis user predominantly uses their prosthesis during bimanual tasks and they appoint visual attention to the sound-side hand, which is used to perform the more complex portion of the task.

Contact-detecting sensors are a simple yet effective advancement in prosthetic research. It is found that contact detection and automated adjustments that mimic natural reflexes have the ability to increase myoelectric hand speed and control of low grip forces with or without visual attention. Visual attention will continue to be a topic of study as well as the contribution of cognitive distraction to fragile grasping performance. Future research will be aimed at validating this as an outcome measure and the conduction of a large clinical study with people who vary in their skills and experience with myoelectric prostheses. It is expected that this technology will improve the user's confidence with fragile grasping tasks, and through utility, increase the amount of tasks they can perform.

REFERENCES

[1] RS. Johansson, G. Westling, "Responses in glabrous skin mechanoreceptors during precision grip in humans," Exp. Brain Res., vol. 66.1, 1987.

[2] B. Matulevich, et al., "Low-cost, compliant contact sensor for fragile grasping with reduced cognitive load," in Myoelec. Cont. Symp., New Brunswick, 2014, pp. 1-3.

[3] D. Baldauf, H. Deubel, "Visual attention during the preparation of bimanual movements," Vision Res., vol. 48.4, pp. 549-563, Feb. 2007.

[4] D. Norwak, S. Glasauer, J. Hermsdörfer, "Force control in object manipulation—A model for the study of sensorimotor control strategies," Neurosci. Biobehav. R., vol. 37.8, pp. 1578-1586, Sept. 2013.

Tactile Sensing Reflexes for Advanced Prosthetic Hands

MR140094
W81XWH-15-1-0149

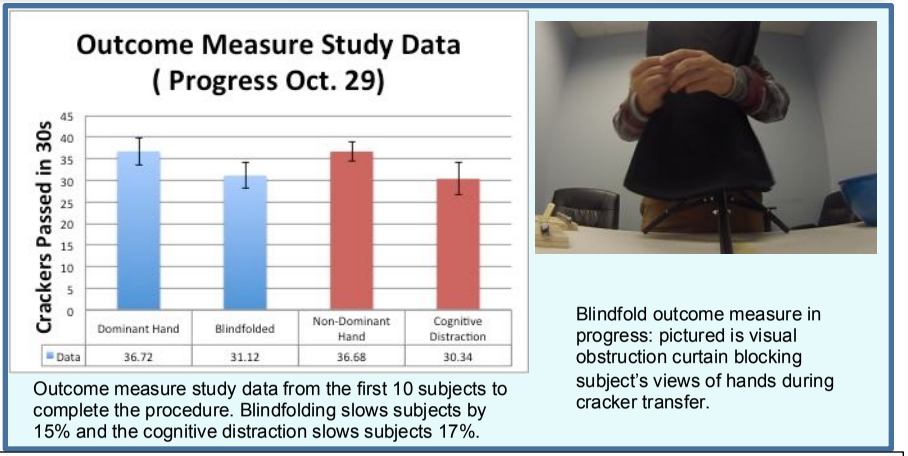
PI: Jeremy A. Fishel, PhD **Org:** SynTouch, LLC **Award Amount:** $1,865,449

Study/Product Aim(s)

- Build NumaTac Sensors that meet Commercial Requirements
- Build integrated prosthetic hand system for clinical studies
- Design outcome measures to evaluate clinical benefit
- Conduct in-office and in-the-field clinical studies
- Organize results for publication and documentation

Approach

Pilot studies have demonstrated that both compliance and contact sensitivity are critical to enabling prosthetic hands to grasp fragile objects. We have developed a tactile sensor which is low-cost and compliant. We will use this sensor to produce intelligent tactile reflexes that make grasping of fragile objects both reliable and intuitive. We will test these results by equipping military amputees with modified hands, performing clinical assessment, and monitoring performance at home.



Outcome measure study data from the first 10 subjects to complete the procedure. Blindfolding slows subjects by 15% and the cognitive distraction slows subjects 17%.

Blindfold outcome measure in progress: pictured is visual obstruction curtain blocking subject's views of hands during cracker transfer.

Accomplishments: 1) Clinical protocol refined, clinical studies begun, preliminary data analyzed. 2) Prosthetic development board design finalized & firmware development proceeding. 3) New finger cores developed, ordered, currently being foam molded. 4) AAOP abstract submitted. 5) Clinical trial phase II VA collaborator identified.

Timeline and Cost

Activities / CY	15	16	17	18	19
Design, Build & Verify Sensors					
Build & Test Prosthetic Hands					
Design & Validate Outcome Meas					
Perform Clinical Studies					
Document and Publish Results					
Estimated Budget ($K)	**179**	**688**	**539**	**310**	**149**

Updated: September 30, 2016

Notes: Dashed lines indicate start and end. Budget is shown for a four year project, occurring over 5 calendar years.

Goals/Milestones

CY15 Goal – Hardware Prototype Development
- ☑ *Identify alternatives for outcome measures*
- ☑ *Explore sensor design parameters*

CY16 Goals – Complete Design of Equipment and Outcome Measures
- ☑ First NumaTac prototypes
- ☑ Final candidate outcome measures identified
- ☐ Final NumaTac design determined

CY17 Goal – Manufacture Equipment, Validate Measures, Start Clinical Studies
- ☐ Completion of prosthetic hand system
- ☐ Validation of outcome measures
- ☐ Clinical studies begun

CY18 Goal – Perform Clinical Studies
- ☐ Perform Clinical Studies

CY19 Goal – Complete Clinical Studies, Documentation
- ☐ Clinical studies completed
- ☐ Final documentation

Comments/Challenges/Issues/Concerns

Timeline for Design Sensors activity extended (dark green), completion of this activity not required until EOY 2016 to maintain overall project schedule.

Budget Expenditure to Date

Projected Expenditure: $537,444, Actual Expenditure: $543,457.74